Minimally Invasive Device

Field of the Invention

The present invention generally relates to the minimally invasive device for minimal traumatic surgery executed in patient's body cavity, and more particularly, for abdominal and thoracic surgery. The invention also includes the methods of minimally traumatic surgical operations and the instruments for their execution.

Background of the Invention

Traditional surgical instrument for minimal invasive surgery (MIS) includes a handle at its proximal part, a housing, and a functional head at its distal end. This head is inserted into patient's body cavity through a port mounted in body cavity wall by trocar. Main requirement of MIS lies in the minimization of the surgical opening dimensions needed for mounting the mentioned port. These dimensions are predetermined with the dimensions of the instrument head. Therefore, the noted MIS requirement also demands the minimization of instrument head dimensions that needs significant developments and investments and not always is achieved. Moreover, the noted MIS requirement interferes with using in MIS the surgical instruments of open surgery. This, to a large extent, withstands MIS spreading.

Endoscopic Surgical Anastomosis Stapling Instrument is disclosed by US Patent 5,333,773. The instrument is designed for bowel circular anastomosis and includes a suture head with a staples' cartridge immovably connected to instrument housing and detachable anvil disposed distally of the staples' cartridge. Diameters of the cartridge and the anvil are equal. The disadvantage of the instrument lies in relatively large dimensions of its part (cartridge) inserted into body cavity through trocar port. This demands relatively large surgical opening in body cavity wall. The necessity of using the suture head of larger diameter inevitably leads to the increase of needed surgical opening.

Instrument for Circular Surgical Stapling is disclosed by US Patent 4,603,693. The instrument has a disposable suture head detachably connected to the housing and consisting of a staples' cartridge and an anvil. The staples' cartridge is connected to the housing before inserting into body cavity. It means, that the instrument, in the same

manner as previous instrument (US Patent 5,333,773), demands relatively large surgical opening in body cavity wall determined with the dimensions of the staples' cartridge. Moreover, the anvil does not have the anvil shaft that eliminates inserting separated anvil into patient bowel and demands complete assembling the suture head before its operation.

Linear Suturing Apparatuses for use on mesentery, omentum and the like are disclosed by US Patents 4,671,445 and 5,027,834. In this case, the suture head has long linear staples' cartridge and anvil and, as a consequence, relatively large transverse dimension of suture head. As a result, the application of these apparatuses in MIS is practically impossible.

Method for Performing a Coronary Artery Bypass is disclosed by US Patent 6,167,889. The surgical operations are performed on closed thorax through a plurality of intercostal ports. The disadvantage of this method is impossibility of using relatively large instruments because of limited dimensions of intercostal gaps. Moreover, the control of internal organs positions and their fixation is very inconvenient and demands many special instruments and ports. This restricts the surgical possibilities and leads to degradation in the quality of surgical procedure.

The common disadvantage of all the above noted patents is the necessity of using traditional trocar devices for ports mounting, for instance disclosed by US Patent 5,690,663. These trocar devices include a port unit and an obturator with sharp distal end for penetrating into body cavity from the outside. Typically, there is a danger of internal organs injury by the obturator distal sharp end at the moment of its entering body cavity. Developed protectors of the obturator sharp end (see the noted US Patent 5,690,663) increase device cost and allow only partial solution of this problem. The mentioned injury danger demands the concentration of surgeon attention and its significant nerves tension.

An Endoscopic Surgical Sealing Device is disclosed by US Patent 5,366,478. The device enables the inserting into body cavity either surgeon's hand or relatively large surgical instrument through a hand port. The disadvantage of such hand port applying is the impossibility of hand port use according to its direct designation during its use as a port for surgical instrument. Using the hand port for surgical instrument insertion does not meet the noted main MIS requirement to minimize the surgical opening. The same relates to another embodiment of this patent with obviously enlarged surgical opening and port for inserting the surgical instruments of various dimensions.

Summary of the Invention

The objective of the present invention is the minimization of surgical openings dimensions in body cavity wall for inserting surgical instruments into body cavity.

Another objective is the minimization of surgical openings number in body cavity.

Another objective is the extension of applying in MIS the surgical instruments of relatively large dimensions.

Another objective is using in MIS main components of surgical instruments used in open surgery.

Another objective is decreasing needed investment for the development of needed surgical instrument set.

Another objective is improving the convenience of surgical operations execution and decreasing the surgeon nerves tension.

Another objective is substantial extension of surgical possibilities and rise in the quality of surgical operations.

Another objective is the decrease of total instruments number needed for surgical operations execution.

Another objective is reducing the total cost of surgical instruments set needed for surgical procedure performance.

Another objective is significant lowering the possibility of patient's internal organ injury during surgical procedure.

Another objective is imparting universal properties to the surgical instruments allowing its use both in MIS and in open surgery.

The above noted objectives are accomplished with a minimal invasive device for minimal traumatic surgery, assembled through at least two – the first and the second surgical openings in a body cavity wall, passing through the first surgical opening during device operation and having an inner unit, an outer unit, and an intermediate part. The latter is an integral part of one of mentioned units and has a free end designed to passing through body cavity wall via the first surgical opening. The maximal transverse dimension of the intermediate part and its free end is substantially lesser than one of the inner unit. The inner unit is designed for inserting into body cavity and withdrawing therefrom through the second surgical opening and has the maximal transverse dimension substantially more than one of the first surgical opening minimally needed for inserting

therethrough the intermediate part. As a result, the insertion of the inner unit into body cavity and withdrawing therefrom through the first surgical opening is impossible. The device also includes a coupling means partly disposed on the intermediate part and having fast acting connectors adapted to operative connecting and disconnecting the inner and outer units while the inner unit is disposed inside body cavity.

The method of preparation and execution of minimally traumatic surgical operations with the above noted minimally invasive device comprises: forming the first and the second surgical openings in body cavity wall, inserting the inner unit into body cavity through the second surgical opening, leading the free end of the intermediate part through body cavity wall via the first surgical opening, connecting the inner and outer units by the fast acting connectors with forming an operational assembly, execution of surgical operations at least by the mentioned operational assembly, disconnecting the inner and outer units after executing needed surgical operations, and withdrawing the device components through the same openings through which they have been inserted: the intermediate part through the first surgical opening and the inner unit from body cavity through the second surgical opening. The second surgical opening can be embodied as a hand port or some enlarged trocar port. The first surgical opening can be carried out as small trocar port with inner diameter of the order of 6-13 mm.

Thus, only small first surgical opening is necessary for inserting surgical instrument into body cavity. In spite of using one some enlarged second surgical opening, substantial decrease of patient's traumatization is achieved since, as a rule, many surgical instruments and, correspondently many first surgical openings, are used in MIS (see, for instance US Patent 6,167,889, fig.11). The present invention allows the use of the inner units of various dimensions and functional designations with the same one outer unit thereby decreasing needed number of the first surgical openings. This also decreases patient's traumatization, reduces needed instrument number and its cost. Moreover, the first surgical opening does not restricts the dimensions of instrument's functional head (inner unit), which is inserted into body cavity in separated form through relatively large second surgical opening. It means, that the present invention substantially extents the surgical possibilities of MIS due to applying in MIS significantly enlarged functional heads, including used in open surgery. The latter enables the application in MIS already developed and well-checked designs of open surgery thereby decreasing the expected investment for R&D. The present invention allows the improvement of operation convenience and the rise in quality of

surgical operations due to the possibility of immediate participation of surgeon's hand inserted through the second surgical opening in surgical manipulation inside body cavity. The latter is especially important for thoracal surgery and, in this case, the present invention provides for the carrying out the second surgical opening, which begins in epigastrium.

In version embodiment, the present invention provides for the execution of the first surgical openings from the inside of body cavity by simplified obturatorless trocar device previously inserted into body cavity through the second surgical opening. In another version, the first surgical opening is executed without trocar device by means of sharp penetrating tip disposed on the free end of device intermediate part. These versions additionally decrease the cost of surgical instruments cost, enhance the operation safety eliminating the danger of internal organs injury by trocar sharp penetrating end, and decrease needed concentration of surgeon's attention caused with this danger.

In version embodiment, the minimally invasive device presents a circular stapler for bowel circular anastomosis, wherein the anvil is disposed distally of the staples' cartridge unit. The anvil unit has the anvil and an anvil shaft. There are also a drive means including a control rod connecting the actuating means and the anvil shaft as well as a drive means connector including an anvil shaft engagement member and a control rod engagement member. The cartridge unit is secured to a body of device intermediate part by units bodies connector and includes a connector lock means eliminating the disconnection of the drive means connector at least during tissue stapling. The anvil and cartridge units form the stapler's inner unit inserted into body cavity and withdrawn therefrom through the second surgical opening. The distal free end of the control rod presents the free end of stapler's intermediate part inserted into body cavity through the first surgical opening. The drive means connector and units bodies connector are fast acting connectors allowing operative connecting and disconnecting the stapler's intermediate part and inner unit when the latter is disposed in body cavity. The mentioned lock means provides reliable stapler operation during tissue suturing. The stapler provides the possibility of the operation according to the above noted method of the present invention with all the noted advantages.

Note, proposed minimally invasive devices are universal instruments allowing their use both in present proposed MIS and in open surgery, as well as in usual MIS as a

combination of traditional miniature functional head of MIS with the outer part of proposed instrument.

Brief Description of the Drawings

Fig.1 shows the assembled circular stapler for bowel circular anastomosis.
Fig.2 shows the cross-section of all the components of the circular stapler.
Fig.3 shows the cross-section of the circular stapler after removing an anvil unit.
Fig.4 shows the distal part of the circular stapler with extended anvil.
Fig.5 shows the circular stapler at the moment immediately before tissue suturing start.
Fig.6 shows the circular stapler at the moment of tissue suturing end.
Fig.7 shows the circular stapler in the state of its insertion into body cavity.
Fig.8 shows the circular stapler with sutured bowel parts secured to stapler.
Fig.9 shows the circular stapler and sutured bowel parts at the moment of suturing start.
Fig.10 shows the circular stapler and sutured bowel parts at the moment of suturing end.
Fig.11 shows obturatorless trocar device with detachable penetrating tip.
Fig.12 shows the fixation member fotrocar port fixation in body cavity wall.
Fig.13 shows the piercing the body cavity wall by obturatorless trocar.
Fig.14 shows the obturatorless trocar at the moment of its going out of body cavity wall.
Fig.15 shows the trocar port introduced into body cavity wall by obturator less trocar from the inside of body cavity.
Fig.16 shows the trocar port introduced into body cavity wall by obturatorless trocar from the outside of body cavity.

Detailed Description of the Invention

With reference now to the drawings, the minimally invasive device in the form of circular stapler according to the present invention includes an inner unit A, an intermediate part B, and an outer unit C (see fig.1). The inner unit A has anvil unit 20 including anvil 21, malleable web 42, staple bending grooves 64, and anvil shaft 22, as well as cartridge unit 23 including inner unit body 24, cartridge carrier 65, cartridge carrier base 66, cartridge 25 having a plurality of staples 26, and circular knife 27 interacting with malleable web 42 during cutting off excessive bowel tissue after bowel parts suturing. In

assembled stapler, anvil 21 is disposed distally of cartridge 25. Cartridge 25 is movable in axial direction and underspringed by spring 28 relative to inner unit body 24. The intermediate part B has intermediate part body 29 housing the drive means in the form of control rod 30 connecting actuating means 31 with anvil shaft 22. Cartridge unit 23 can be connected to / disconnected from intermediate part body 29 by units bodies connector 32 in the form of thread 33 on inner unit body 24 and 34 on intermediate part body 29. Anvil shaft 22 can be connected to / disconnected from control rod 30 by drive means connector 35 including an anvil shaft engagement member in the form of circular projection 36 on the proximal free end of anvil shaft 22 and a control rod engagement member in the form of circular recess 37 of collet 38 on the distal free end of control rod 30. Cartridge unit 23 also includes a connector lock means in the form of bushing 39 immovably connected with cartridge carrier base 66 and hampering transverse broadening the collet 38 thereby eliminating the disconnection of drive means connector 35 during tissue stapling (figs.5, 6). There are also means for mutual angular orientation of anvil 21 and cartridge 25 in the form of inner grooves 40 and outer oblong projections 41. Outer unit C includes handle 43 and actuating means 31. The latter comprises a proximal end portion of control rod 30 in the form of rack 44 interacting with toothed wheel 45 manually controlled by wheel handle 68 and designed for control rod retraction to bring together anvil 21 and cartridge 25 and bowel parts before their suturing as well as for anvil extension distally to withdraw drive means connector 35 from locking bushing 39 for the disconnection of connector 35 after bowel part suturing. Outer unit C also includes lever 46 rotatable around axle 67 and designed for transmitting to control rod 30 the force intended for bending staples 26 and thereby immediate suturing bowel parts. Lever 46 is provided with engagement member 47 undespringed by spring 48, sliding in guides 49, and having upper fork 50 for engaging notch 51 of control rod 30 at the moment of bringing together anvil 21 and cartridge 25 immediately before staples' bending and bowel part suturing (fig.5). After putting down locking protector 52 (fig.6), surgeon brings together handle 43 and lever 46 thereby compressing spring 28 and displacing cartridge 25 proximally. As a result, staples 26 are gone out of cartridge 25 and bent by grooves 64 of anvil 21 thereby suturing bowel parts (fig.10). At the same time, knife 27 cuts off excessive bowel tissue. Then, surgeon puts down knob 53 of engagement member 47 thereby disengaging fork 50 and notch 51 and allowing the extension distally of control rod 30 by wheel 45 to provide the possibility of disconnecting the drive means connector 35 (fig.4).

Intermediate part B and, specifically, its body 24, forms an integral part with outer unit C and has distal free end 54 designed for passing through body cavity wall 55 via first surgical opening 56 or via trocar port 57 mounted in first surgical opening 56 (fig.7). Maximal transverse dimension of intermediate part B, specifically of its body 29, is substantially lesser than maximal transverse dimension of inner unit, specifically of cartridge 25. Inner unit A including anvil unit 20 and cartridge unit 23 is designed for inserting into body cavity and withdrawing therefrom through second surgical opening 59 or through hand port 60 mounted in second surgical opening 59. Maximal transverse dimension of inner unit A, specifically of cartridge 25, is substantially more than maximal transverse dimension of first surgical opening 26 or inner diameter of trocar port 57 minimally needed for inserting therethrough intermediate part B. As a result, the insertion of inner unit A into body cavity 58 and withdrawing therefrom through first surgical opening 56 or trocar port 57 is impossible. A coupling means of circular stapler including units bodies connector 32 and drive means connector 35 are adapted to operative connecting and disconnecting inner unit A and the block of outer unit – intermediate part while inner unit A is disposed inside body cavity 58.

Method of preparation and execution of minimally traumatic surgical operations implemented with above described circular stapler comprises forming first surgical opening 56 in body cavity wall 55 by trocar device and mounting trocar port 57 therein, and forming second surgical opening 59 and mounting hand port 60 therein. First surgical opening 56 has minimally needed maximal transverse dimension substantially lesser than one of second surgical opening 59 and of cartridge 25. The same relates to the relationship of inner diameters of trocar port 57 and hand port 60, respectively. Further, method provides for inserting inner unit A including anvil unit 20 and cartridge unit 23 into body cavity 58 through hand port 60, and distal free end 54 of control rod 30 and distal end of intermediate part body 29 into body cavity 58 through trocar port 57. Then, inner unit A is connected to outer unit C through intermediate part B by coupling members with forming an operation assembly. As applied to the circular stapler, this connection is executed in the following manner: first, cartridge unit 23 is connected to intermediate part body 29 by units bodies connector 32, then cartridge 25 is inserted into bowel part 61 through lateral incision 62 and bowel part 61 is secured to control rod 30 from the distal side of cartridge 25, then anvil 21 is inserted into bowel part 63 and the latter is secured to anvil shaft 22, then anvil unit 20 is connected to control rod 30 by drive means connector 35 (fig.8).

Further, surgeon executes suturing the bowel parts 61 and 63, first bringing together anvil 21 and cartridge 25 by wheel 45 (fig.9) and, then, bringing together lever 46 and handle 43 (fig.10). After bowel suturing, surgeon withdraws inner unit A from bowel through incision 62, disconnects units bodies connector 32 inside body cavity 58, and withdraws inner unit A from body cavity 58 through hand port 60. All the manipulations in body cavity are executed with the participation of surgeon hand inserted into body cavity through hand port 60.

As applied to thoracal cavity, the operation method provides for forming at least two – the first and the second surgical openings in patient's thoracal cavity: second surgical opening begins below a costal arch in epigastrium and passes into thoracal cavity to provide the access of surgeon's hand into thoracal cavity and designed for inserting therethrough device inner unit into thoracal cavity and for participating the surgeon hand in surgical manipulations inside thoracal cavity; the first surgical opening located in intercostal gap, designed for leading the free end of intermediate part through thoracal cavity wall, and having minimally needed maximal transverse dimension substantially lesser than one of the second surgical opening and the inner unit. Further, the method includes: inserting the inner unit into thoracal cavity through the second surgical opening, leading the free end of intermediate part through body cavity wall via the first surgical opening, and connecting the inner unit to the outer unit by the coupling members with forming an operational assembly. As a result, an assembly inner part is disposed inside thoracal cavity, an assembly outer part is disposed outside thoracal cavity, and the intermediate part is passing through the first surgical opening. After the execution of needed surgical operations by the mentioned operational assembly and surgeon hand disposed inside body cavity, surgeon disconnects the inner unit from the outer unit, withdraws the intermediate part from the first surgical opening and the inner unit from thoracal cavity through the second surgical opening.

In version embodiment, the second surgical opening is passed through abdominal cavity and, further, through patient's diaphragm into thoracal cavity.

In version embodiment, a hand port is mounted into the second surgical opening and inserting the inner unit into thoracal cavity and its holding during its connecting with the outer unit are executed by surgeon's hand inserted into thoracal cavity through the hand port.

In version embodiment, the first surgical opening in intercostal gap of thoracal cavity wall is executed by a trocar device with mounting a trocar port in the first surgical opening.

Thus, only small first surgical opening 56 is necessary for inserting surgical instrument into body cavity 58. Specifically, diameter of intermediate part body 29 determining the diameter of first surgical opening lies in the limits of 6-13 mm. Upon using many surgical instruments, this provides substantial decrease of patient's traumatization. There is a possibility of using the inner units of various dimensions adapted to connection with the same outer unit C and intermediate part B. This allows the decrease of total instrument cost and needed number of first surgical opening. The latter additionally decreases patient's traumatization. The present invention enables the use of the inner units without substantial restrictions their dimensions due to their insertion into body cavity through hand port. As a result, the potentialities of MIS are substantially extended. Moreover, this allows the adapting for MIS various functional heads applied in open surgery thereby reducing the time and investments for R&D. The use of hand port 60 provides free access of surgeon hand into body cavity 58 and its participation in surgical manipulations that significantly improves an operation convenience.

In version embodiment (not shown), the minimally invasive device has an electro-mechanical, or pneumatic actuating means and a drive means as distinct from mechanical actuating means 31 and drive means 30 of the above circular stapler.

In version embodiment (not shown), the second surgical opening is executed by a trocar device, which has internal dimensions allowing the insertion of the inner unit into body cavity through its trocar port. This inserting and subsequent holding the inner unit during its connection with the outer unit are executed by an inner unit holder inserted into body cavity through the mentioned trocar port.

In version embodiment, the inner unit and intermediate part are made as an integral unit, the coupling means are disposed on the intermediate part and on the outer unit and adapted to the connection / disconnection beyond body cavity after inserting the inner part into body cavity through the second surgical opening and leading the intermediate part free end via the first surgical opening from the inside to the outside of body cavity.

In version embodiment (figs.11-15), the trocar device used for the execution of first surgical opening 56 has inner part 69 in the form of a trocar portal unit including trocar port 70 with inner unit 71 comprising sealing means 72, which presents an elastic washer

with a few central slots operating both as a trocar valve and a sealing member. Further, the trocar device includes intermediate part 73 as a part of trocar port 70 and detachable obturatorless penetrating unit 74 having a sharp penetrating knife 75 and resilient protector member 76. There is also the outer unit presenting fixation member 77. Fixation member 77 has resilient sides 78, which, under their compression by surgeon, increase the distance between clamping members 79 thereby allowing the montage of fixation member 77 onto trocar port 70. The latter has indented surface 80 facilitating its engagement with members 79.

In version embodiment (not shown), trocar port 70 has smooth external surface, which engages fixation member 77 due to a clipping means located on fixation member 77.

The trocar inner part 69 is inserted into body cavity 58 through the second surgical opening 59, and surgeon pierces body cavity wall 55 by trocar inner part 69 from the inside of body cavity 58 up to the abutment of the inner unit 71 against body cavity wall 55 thereby forming the first surgical opening 56 and simultaneously mounting the trocar port 70 therein. During body cavity wall piercing, resilient protector member 76 is compressed by body's tissue and cut through by knife 75 allowing knife 75 cutting the tissue (fig.13). At the moment of penetrating unit going out of body wall (fig.14), protector member 76 is returned to its initial position under its elasticity forces thereby protecting knife 75. Then, surgeon removes detachable penetrating unit 74 and mounts fixation member 77 on the exterior end of trocar port 70 thereby securing trocar port 70 in body cavity wall (fig.15). This trocar device is simpler, cheaper, and safer in use in comparison with traditional versions having the obturator and inserted from the outside of body cavity.

In version embodiment (fig.16), the above described trocar device is inserted into body cavity wall from the outside of body cavity. In this case, unit 71 with sealing means 72 presents the device outer unit and fixation member 77 presents the inner unit, which is mounted onto trocar port 70 inside body cavity by surgeon's hand inserted into body cavity through second surgical opening 59 after removing penetrating unit 74 from the trocar port end disposed inside body cavity.

Similar to last version of the use of fixation member 77, this member inserted into body cavity through the second surgical opening can be used as a fixation member of traditional trocar devices by its mounting onto trocar port distal end inside body cavity.

In version embodiment (not shown), the free end of surgical instrument intermediate part is provided with a penetrating tip identical to penetrating unit 74 and designed for piercing body cavity wall to form the first surgical opening and simultaneously to insert the intermediate part into formed first surgical opening. This allows the exclusion of trocar devices from instruments set and surgical procedure thereby substantially lowering set's cost and significantly simplifying and reducing surgical procedure.

In version embodiment (not shown), the body of the inner unit of assembled device is rotatable around the device longitudinal axis and relative to the body of the outer unit thereby providing the property inherent in traditional MIS instrument.

In version embodiment (not shown), the inner unit presents a suturing head of a linear stapler.

In version embodiments, the minimally invasive device according to the present invention is made as: an electrosurgical instrument, or a camera, or a surgical laser, or a medical endoscope. These devices include all the main features of the present invention such as outer unit, inner unit, intermediate part, and coupling means with their mutual arrangement, general designation, and use identical with those of the above described surgical stapler.

The present invention, in principle, allows the use for MIS the instrument set including one hand port, one trocar device, one outer unit, and a plurality of the inner units of various functional designation and transverse dimensions adapted to connecting and using with one outer unit. In another version embodiment, the instrument set includes one hand port, a few (restricted number) trocar devices and outer units of the same dimensions, and a plurality of various inner units needed for the implementation of definite surgical procedure.

Proposed minimal invasive device consisting of detachable inner and outer units is universal instrument allowing its use both in present proposed MIS version and in usual open surgery, as well as in traditional MIS as a combination of traditional miniature functional head (inner unit) and the outer part of proposed device.